



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,500	11/21/2003	Joseph Chappell	8064-005-CIP-2	8924
32301	7590	01/05/2010	EXAMINER	
CATALYST LAW GROUP, APC 9710 SCRANTON ROAD, SUITE S-170 SAN DIEGO, CA 92121			KALLIS, RUSSELL	
			ART UNIT	PAPER NUMBER
			1638	
			MAIL DATE	DELIVERY MODE
			01/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/717,500	Applicant(s) CHAPPELL ET AL.	
	Examiner RUSSELL KALLIS	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-21 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-21 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 10-21 and 24 are pending and examined

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 10-21 remain and 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION. This rejection is maintained for the reasons of record set forth in the Official action mailed 6/01/2009. Applicant's arguments filed 10/29/2009 have been considered but are not deemed persuasive.

Applicant asserts that reciting "produced in the absence" and "not produced in the absence" have been removed from the claims (response page 4). The claim recites "the production of at least one isoprenoid sesquiterpene synthase reaction product that is not produced by either the first or the second isoprenoid sesquiterpene synthase polypeptide domains alone". The specification shows that there are no novel products produced by any chimeric sesquiterpene synthase (see figures 4 and 5), so there is not any product produced by a chimeric sesquiterpene synthase that is not produced in the absence of one of the two domains. Because a dependent claim must comprise the limitations of a claim from which it depends, claim 10 and all claims dependent upon claim 10 are included in the rejection. Applicant is invited to point to where in

Art Unit: 1638

the specification support can be found for the production of a novel sesquiterpene (not produced by either the first or second domains alone) by a chimeric sesquiterpene synthase.

Written Description

Claims 10-21 remain and 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 6/01/2009. Applicant's arguments filed 10/29/2009 have been considered but are not deemed persuasive.

Applicant asserts that an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, they were in possession of the invention and that the claims now have specific language that recites domains involved in the chimeric proteins and relevant identifying characteristics such that there is sufficient structural and functional detail (response page 5) and points to the specification to in paragraphs [0037] and [0045] all of which have a ratio determining domain present. Applicants' claims are not limited by a ratio determining domain yet the specification teaches that a ratio determining domain is required for the activity of the chimeric polypeptide as claimed. Amending Claim 10 to recite wherein the two product specific domains of the chimeric sesquiterpene synthase are interrupted by a product ratio determining domain would obviate those portions of the rejection under 112 1st written description drawn to the lack of a structure function relationship.

Enablement

Art Unit: 1638

Claims 10-21 and claim 24 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule encoding a for DNA encoding a chimeric isoprenoid sesquiterpene synthase polypeptide, wherein said chimeric isoprenoid synthase polypeptide comprises a first sesquiterpene synthase domain joined to a second different sesquiterpene synthase domain, interrupted by a ratio determining domain; such that the chimeric isoprenoid sesquiterpene synthase polypeptide encoded by the DNA catalyzes the production of at least one isoprenoid reaction product that is not produced in the absence of the second isoprenoid synthase polypeptide and another product that is produced in the absence of the second domain; and vectors thereof, and plant cells and plants transformed therewith, does not reasonably provide enablement for DNA encoding a chimeric isoprenoid sesquiterpene synthase polypeptide, wherein said chimeric isoprenoid synthase polypeptide comprises a first isoprenoid synthase domain joined to a second different isoprenoid synthase domsin such that the chimeric isoprenoid sesquiterpene synthase polypeptide encoded by the DNA catalyzes: (1) the production of at least one isoprenoid reaction product that is not produced in the absence of either of the first and the second isoprenoid synthase polypeptide domains; or the production of multiple sesquiterpene products from a chimeric sesquiterpene synthase absent a ratio determining domain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 6/01/2009. Applicant's arguments filed 10/29/2009 have been considered but are not deemed persuasive.

Art Unit: 1638

It is important to note the change in the enablement scope from the previous rejection. The Examiner appreciates Applicants' point that the DDXXD domain is not the ratio determining domain. The Examiner apologizes for this oversight. Nonetheless, the requirement for a ratio determining domain is of record in the case.

On page 7 of the response Applicant has not stated fully the enabled portion from the previous office action. The examiner has not conceded enablement for a polypeptide, wherein said chimeric isoprenoid sesquiterpene synthase polypeptide comprises two polypeptide domains: a first isoprenoid sesquiterpene synthase polypeptide domain joined to a second different isoprenoid sesquiterpene synthase polypeptide domain such that the chimeric isoprenoid sesquiterpene synthase polypeptide encoded by the DNA catalyzes the production of at least one isoprenoid sesquiterpene synthase reaction product that is not produced by the first isoprenoid sesquiterpene synthase polypeptide domain alone. The previous rejection recited "astride a ratio determining domain of DDXXD", that has been modified to "a ratio determining domain". Applicant has not addressed the enablement rejection over the lack of ratio determining language in the claims.

In addition, since the publication dates of the cited reference Schalk and Croteau PNAS, are well after the date of the claimed priority (4/12/1996) of the instant application the references show that the state of the art did not and still does not support Applicant's broad claim to chimeric isoprenoid sesquiterpene synthases as broadly claimed in claim 10; and contradict Applicant's assertions that the prior art and the relative skill of those in the art provide enablement for making and using the broadly claimed genus of chimeric isoprenoid sesquiterpene synthase polypeptides or provide evidence that the degree of unpredictability is

Art Unit: 1638

overcome by one of ordinary skill because the work of Schalk and Croteau did not result in the formation of a ratio of products of the two hydroxylases.

Given the unpredictability in the art as stated previously and supra, undue trial and error experimentation would be needed to make and clone a multitude of non-exemplified isoprenoid sesquiterpene synthase domains in combination to create a functional sesquiterpene synthase chimera and to test them in a myriad of non-exemplified expression systems for a multitude of non-exemplified isoprenoid sesquiterpene products. Therefore, the invention is not enabled for the full scope of the claims.

No claim is allowed.

Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Russell Kallis/
Primary Examiner, Art Unit 1638
December 29, 2009